

March 19, 2004

Jesse Polansky, MD, MPH  
Centers for Medicare & Medicaid Services  
Coverage and Analysis Group  
7500 Security Blvd.  
C1-09-06 Mail Stop  
Baltimore, Maryland 21244

Dear Dr. Polansky:

**Formal Request for Reconsideration of the National Coverage Decision (NCD) for Insulin Pumps**

Medtronic MiniMed formally requests that you reconsider Section 60-14 under Track #1 of your established coverage reconsideration process. We request that you revise Section A, “Continuous Subcutaneous Insulin Infusion Pumps (CSII) (Effective for Services Performed on or after 4/21/2000)” and remove the C-peptide testing requirement as a condition of Medicare coverage for insulin pumps. We have provided specific supporting documentation in the attached request and have included all information for this reconsideration request to be considered a “formal” request per the Federal Register notice of September 26, 2003. We have included the following information in both the electronic format and enclosed binders:

1. Formal Request for Reconsideration
2. Timeline of correspondence and previous CMS meeting dates pertaining to this C-peptide issue
3. Description of the insulin pump and benefit category, including FDA labeling
4. CMS Decision memorandum #CAG00092N
5. Summary analysis of why C-peptide testing is not a valid inclusion criteria for insulin pump therapy
6. Supporting Clinical Studies (specific to C-peptide testing, not insulin pump studies)

We understand the American Association of Clinical Endocrinologists and several key opinion leaders will be sending letters to CMS supporting this request to eliminate C-peptide criteria from the NCD.

This reconsideration request and the supporting documentation enclosed is specific to C-peptide testing. Please let us know if you need additional information. We look forward to working with you on this formal request for reconsideration of the insulin pump NCD. Patty Curoe, RN (Strategic Reimbursement Manager) will be the main contact for Medtronic MiniMed. Patty’s email address is [patty.ann.curoe@medtronic.com](mailto:patty.ann.curoe@medtronic.com); cell phone is (303) 570-2159 or office number is (303) 526-7604. We look forward to hearing back from you on the next steps in the formal review process. We are available to

meet in person to discuss further at your convenience. Thank you in advance for your review and consideration of this important issue.

Sincerely,

Alan O. Marcus, MD, FACP  
Director of Medical Affairs, Medtronic MiniMed  
Associate Clinical Professor, USC Keck School of Medicine  
Chief Clinician, South Orange County Endocrinology and Research

cc: Jim Sorace, MD, MS                      CMS Medical Officer  
Betty Shaw                                      Policy Analyst  
Phil Levin, MD                                 Medical Director, Diabetes Center at Mercy